

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

IN RE FLINT WATER LITIGATION

Case No. 5:16-cv-10444-JEL-MKM
Hon. Judith E. Levy

This Document Relates To:

Gaddy et al. v. Flint et al.

Meeks et al. v. Flint et al.

Case No. 5:17-cv-11166-JEL-MKM

Case No. 5:17-cv-11165-JEL-MKM

**DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH
AMERICA, INC., AND VEOLIA WATER NORTH AMERICA
OPERATING SERVICES, LLC’S MOTION TO EXCLUDE THE
TESTIMONY AND REPORTS OF WILLIAM G. BITHONEY, M.D.**

Pursuant to Federal Rules of Evidence 702 Defendants Veolia North America, LLC, Veolia North America, Inc., and Veolia Water North America Operating Services, LLC (VNA) move to exclude the testimony and reports of Dr. William G. Bithoney. Dr. Bithoney’s testimony and reports should be excluded because they are unreliable, not helpful to the tier of fact, and/or substantially more prejudicial than probative.

As Local Rule 7.1(a) requires, VNA conferred with Plaintiffs’ counsel concerning this motion. After VNA explained the nature and legal basis for the motion, Plaintiffs’ counsel said that they would oppose it.

Respectfully submitted,

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Dated: May 11, 2021

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**DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH
AMERICA, INC., AND VEOLIA WATER NORTH AMERICA
OPERATING SERVICES, LLC'S BRIEF IN SUPPORT OF THEIR
MOTION TO EXCLUDE THE TESTIMONY AND REPORTS
OF WILLIAM G. BITHONEY, M.D.**

STATEMENT OF THE ISSUE PRESENTED

1. Should the Court exclude the testimony and reports of Dr. William G. Bithoney under Federal Rules of Evidence 702, 402, and 403 because they are unreliable, not helpful to the trier of fact, and/or substantially more prejudicial than probative?

VNA answers: “Yes.”

Plaintiffs answer: “No.”

CONTROLLING OR MOST APPROPRIATE AUTHORITIES

Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)

Lowery v. Enbridge Energy Ltd. P'Ship, 500 Mich. 1034 (2017)

McClain v. Metabolife Int'l, Inc., 401 F.3d 1233 (11th Cir. 2005)

Nelson v. Tenn. Gas Pipeline Co., 243 F.3d 244 (6th Cir. 2001)

Pluck v. BP Oil Pipeline Co., 640 F.3d 671 (6th Cir. 2011)

Powell-Murphy v. Revitalizing Auto Communities Env't Response Tr.,
—Mich. App.—, No. 348690, 2020 WL 4722070 (Mich. Ct. App. Aug. 13, 2020)

Tamraz v. Lincoln Elec. Co., 620 F.3d 665 (6th Cir. 2010)

Fed. R. Evid. 702

TABLE OF CONTENTS

	Page
INTRODUCTION	1
BACKGROUND	3
LEGAL STANDARD.....	8
ARGUMENT	9
I. DR. BITHONEY’S OPINION ABOUT GENERAL CAUSATION IS UNRELIABLE	10
II. DR. BITHONEY’S SPECIFIC-CAUSATION OPINION IS UNRELIABLE	17
A. Dr. Bithoney Failed To Conduct A Reliable And Sufficient Exposure Assessment.....	18
1. Dr. Bithoney Lacked A Sufficient Factual Basis For His Conclusion That Plaintiffs Were Exposed To Elevated Levels Of Lead In Drinking Water	19
a. Dr. Bithoney Did Not Reliably Assess The Facts About Specific Plaintiffs	19
b. The Population-Level Studies And Data That Dr. Bithoney Cites Do Not Support His Opinion That Plaintiffs Were Exposed To Elevated Levels Of Lead In Drinking Water.....	24
2. Plaintiffs’ Blood Lead Levels Do Not Support Dr. Bithoney’s Exposure Assessment.....	29
3. Plaintiffs’ Bone Lead Levels Do Not Provide Reliable Information About Plaintiffs’ Exposure To Lead In Flint’s Water During The Water Crisis.....	32
a. The pXRF Methodology Does Not Accurately Measure Bone Lead In Children.....	32
b. The Bone-Lead Measurements Do Not Provide A Reliable Basis For Dr. Bithoney’s Opinion That Plaintiffs Were Exposed To A Harmful Amount Of Lead	33

TABLE OF CONTENTS **(continued)**

	Page
c. The Bone-Lead Measurements Cannot Show That Plaintiffs Suffered Lead Exposure Resulting From The Water Crisis	35
B. Dr. Bithoney Does Not Provide Reliable Testimony About The Level Of Exposure Necessary To Cause Plaintiffs’ Injuries	38
1. Dr. Bithoney Fails To Provide Any Evidence That Plaintiffs’ Bone Lead Levels Were Sufficient To Cause Their Injuries	38
2. Dr. Bithoney’s “No Safe Level” Opinion Is Not Admissible	40
a. Courts Regularly Exclude As Unreliable Expert Testimony That Ignores The Relationship Between Dose And Toxicity	40
b. Dr. Bithoney’s Opinion That Any Exposure Is Sufficient To Cause Injury Is Unreliable.....	43
3. Dr. Bithoney’s Opinions About The Association Between Various Health Effects And Blood Lead Levels [REDACTED] [REDACTED] Are Unreliable	46
C. Dr. Bithoney Did Not Reliably Exclude Alternative Sources Of Lead	50
III. DR. BITHONEY’S OPINIONS ABOUT PLAINTIFFS’ POTENTIAL FUTURE INJURIES ARE UNRELIABLE	55
IV. DR. BITHONEY’S OPINIONS DO NOT FIT PLAINTIFFS’ THEORY OF LIABILITY WITH RESPECT TO VNA	57
CONCLUSION	59

INTRODUCTION

Dr. William Bithoney is a medical doctor with a background in clinical treatment of lead-exposed children. This motion focuses on Dr. Bithoney's opinions about the four children who are scheduled for the initial bellwether trial: A.T., E.S., D.W., and R.V. (Plaintiffs).¹ Dr. Bithoney addresses causation. His principal causation opinion is that Plaintiffs' alleged injuries could have been, and in fact were, caused by their exposure to an alleged increase in the amount of lead in Flint's water during the water crisis. That opinion is unreliable and should be excluded. Moreover, Dr. Bithoney's additional opinions that Plaintiffs' exposures [REDACTED] [REDACTED] as they grow older, and that they are at an increased risk of experiencing various health conditions, are irrelevant and would be substantially more prejudicial than probative.

First, Dr. Bithoney's opinion that lead exposure is capable of causing Plaintiffs' claimed injuries lacks a scientific basis. Plaintiffs' expert neuropsychologist, Dr. Mira Krishnan [REDACTED] [REDACTED] [REDACTED]. Dr. Bithoney does not identify a single study demonstrating an association—much less causation—between lead

¹ To be precise, the guardians of E.S., A.T., R.V., and D.W. are the actual plaintiffs. But for the sake of simplicity, VNA will refer to E.S., A.T., R.V., and D.W. as Plaintiffs.

exposure and either [REDACTED] While his report cites one study discussing the possible connection between [REDACTED], it is insufficient to support his causation opinion.

Second, Dr. Bithoney's opinion that Plaintiffs were exposed to a sufficient amount of lead in Flint's water to cause their injuries also is unreliable. Dr. Bithoney lacks reliable scientific support for his opinion that Plaintiffs were exposed to material amounts of additional lead after the City of Flint began drawing its water from the Flint River. Moreover, Dr. Bithoney fails to quantify Plaintiffs' exposure. Instead, in opining that Plaintiffs suffered the degree of exposure necessary to cause their claimed injuries, Dr. Bithoney relies on the legally invalid theory that any incremental exposure to lead is harmful. Few of the studies that Dr. Bithoney cites in support of his opinions address the specific health effects claimed by Plaintiffs, and none suggests that *any* amount of incremental exposure can cause harm.

Third, Dr. Bithoney fails to reliably identify and rule out possible alternative causes of Plaintiffs' claimed health conditions. In particular, he does not consider the possibility that the conditions were caused by non-environmental factors, environmental toxins other than lead, lead from sources other than water, or earlier lead spikes in Flint's water.

Fourth, Dr. Bithoney intends to testify about the association between lead exposure and various adverse health conditions that Plaintiffs do not claim to have

experienced. That testimony should be excluded as irrelevant and as substantially more prejudicial than probative. Dr. Bithoney's opinion that Plaintiffs have a higher likelihood of developing these conditions in the future is entirely speculative. And his opinion that Plaintiffs' [REDACTED]

[REDACTED] is based on a novel scientific theory that has not been reliably applied to the conditions alleged here.

Finally, Dr. Bithoney's opinions do not "fit" Plaintiffs' theory of liability against VNA. VNA did not begin its engagement until February 2015, long after the City began using Flint River water. Dr. Bithoney does not attempt to demonstrate that Plaintiffs' injuries were attributable to exposures that occurred after VNA's involvement. In fact, Dr. Bithoney's exposure assessments suggest just the opposite—that Plaintiffs significantly reduced (or entirely ceased) using unfiltered Flint water months before VNA was involved.

BACKGROUND

Dr. Bithoney opines that Plaintiffs' injuries were caused by their exposure to lead in Flint's water between April 2014 and October 2015, when the City was sourcing its water from the Flint River. For each Plaintiff, Dr. Bithoney prepared a report addressing the following issues:

Plaintiffs' Injuries. Dr. Bithoney states that he did not perform physical examinations or neurological assessments of Plaintiffs. Ex. 2, Bithoney Report (E.S.) 1; Ex. 3, Bithoney Report (A.T.) 1; Ex. 4, Bithoney Report (R.V.) 1; Ex. 5, Bithoney Report (D.W.) 1. Instead, he relies entirely on the examinations and diagnoses by Dr. Krishnan. See Ex. 13, Bithoney Dep. 217:20-218:20, 232:13-20 (Dep.). [REDACTED]

[REDACTED] See Report (E.S.) 7; Report (A.T.) 6; Report (R.V.) 6; Report (D.W.) 8. Dr. Bithoney opines that these injuries were caused by exposure to lead in Flint water. See Report (E.T.) 13; Report (A.T.) 11-12; Report (R.V.) 12; Report (D.W.) 12.

Harmful Effects of Lead. In discussing the health effects associated with lead exposure, Dr. Bithoney does not focus on the [REDACTED]
[REDACTED] Rather, Dr. Bithoney provides a general discussion of various physical and neuropsychological effects that he maintains are associated with lead exposure.

With respect to physical health effects, Dr. Bithoney states that lead causes “decreased kidney function, hypertension, cardiac disease and essential tremor,” as well as an “increased risk of death from stroke.” Report (E.S.) 11; Report (A.T.) 10; Report (R.V.) 10; Report (D.W.) 10. As for neuropsychological effects, he opines

that lead exposure is associated with, among other things, lower scores on IQ tests, poorer performance with respect to certain cognitive functions (*e.g.*, short-term memory and non-verbal reasoning), and ADHD. Report (E.S.) 11-12; Report (A.T.) 10-11; Report (R.V.) 10-11; Report (D.W.) 10-11. Dr. Bithoney also opines that “any level” of lead is toxic and that researchers have observed certain cognitive effects at blood lead levels as low as 1 µg/dL. Report (E.S.) 9; Report (A.T.) 10; Report (R.V.) 10; Report (D.W.) 10.

Plaintiffs’ Exposures to Lead. Dr. Bithoney summarizes various third-party studies and investigations related to the alleged increase in water lead levels in Flint during the time when the City drew its water from the Flint River. *E.g.*, Report (E.S.) 4 (discussing Virginia Polytechnic Institute and State University (Virginia Tech) study and FAST pipe replacement); *id.* at 9 (discussing a 60 Minutes report). He also discusses Plaintiffs’ exposure to tap water, noting that Plaintiffs’ parents told him that Plaintiffs drank between three and six glasses of water per day. *Id.* at 8; Report (A.T.) 7; Report (R.V.) 7; Report (D.W.) 7.

However, Dr. Bithoney also conceded that each of the Plaintiffs stopped drinking tap water at home altogether or reduced the amount of tap water they drank at different points during the water crisis. *See* Report (E.S.) 3 (when she learned about the lead contamination of the water, Plaintiff’s mother “stopped using the Flint water for drinking but continued to bathe and wash dishes with it”); Report (A.T.) 3

(Plaintiff “cut back her drinking of Flint water . . . after free bottled water was made available in 2015”); Report (R.V.) 2 (Plaintiff’s mother “reported that she stopped using the kitchen sink for drinking water as soon as she learned about the [lead] poisoning danger in December 2014”); Report (D.W.) 4 (“In late Summer 2014 mother began using bottled water for drinking, cooking and also to bathe her children.”).

Dr. Bithoney acknowledges that he has no information about the actual (or even estimated) water lead levels in Plaintiffs’ homes during the period when the City was drawing its water from the Flint River. Dep. 121:14-123:5, 140:6-11, 228:14-229:18. He explains that Plaintiffs’ parents reported that their water was discolored or had an unpleasant odor, and he states that the water’s color and odor suggest (but do not prove) that it contained lead. Report (E.S.) 4; Report (A.T.) 8; Report (R.V.) 8; Report (D.W.) 9.

Plaintiffs’ Blood Lead And Bone Lead Levels. Dr. Bithoney acknowledges that Plaintiffs’ blood lead levels were tested either during or soon after the water crisis and that the tests [REDACTED]

[REDACTED]. Specifically, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] In addition, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dr. Bithoney maintains that these results should be disregarded and instead the focus should be on Plaintiffs' bone lead levels, [REDACTED]

[REDACTED] Report (E.S.) 4-5; Report (A.T.) 4; Report (R.V.) 4; Report (D.W.) 3. At the same time, however, Dr. Bithoney admitted at his deposition that he has no experience with bone lead testing and has never relied on bone lead levels to evaluate children's lead exposures. Dep. 44:17-45:3, 73:3-10.

Future Injuries and Effects of Exposure in Adulthood. Finally, Dr. Bithoney opines—without a reliable basis—that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

LEGAL STANDARD

The Supreme Court has charged district courts with a “basic gatekeeping obligation” to ensure that expert testimony is “relevant to the task at hand” and “rests on a reliable foundation.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141, 147 (1999) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). A qualified expert may provide opinion testimony only if it will “help the trier of fact to understand the evidence or to determine a fact in issue.” Fed. R. Evid. 702(a). The expert opinion also must be “based on sufficient facts or data,” must be “the product of reliable principles and methods,” and must be the result of the expert “reliably appl[ying] the principles and methods to the facts of the case.” Fed. R. Evid. 702(b)-(d).

The Supreme Court has identified four non-exclusive factors for courts to consider when deciding whether an expert’s methodology “rests on a reliable foundation”: (1) “whether a theory or technique can be or has been tested”; (2) “whether it has been subjected to peer review and publication”; (3) “whether a technique has a known or potential rate of error and the existence of standards controlling its operation”; and (4) “whether the theory or technique enjoys general

acceptance in a relevant scientific community.” *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 n.5 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593-94).

As the proponents of the expert testimony, Plaintiffs bear the burden of establishing its admissibility by a preponderance of evidence. *Nelson*, 243 F.3d at 251.

ARGUMENT

Dr. Bithoney’s opinion that Plaintiffs’ alleged injuries were caused by their exposure to high levels of lead in Flint’s water should be excluded for three reasons. First, Dr. Bithoney fails to present reliable scientific evidence that lead, at any level of exposure, can cause the specific conditions that form the basis for Plaintiffs’ claims. Second, Dr. Bithoney lacks an adequate basis for his opinion that Plaintiffs were in fact exposed to a sufficient amount of lead to cause their injuries. Third, Dr. Bithoney does not employ a reliable methodology for ruling out the wide array of potential causes of Plaintiffs’ alleged cognitive injuries other than their ingestion of lead-contaminated water during the water crisis.

Dr. Bithoney’s speculation about how Plaintiffs’ alleged exposures may affect them in the future is also inadmissible. His opinion that the full extent of Plaintiffs’ injuries will not be evident until later in life is based on a novel theoretical model that cannot reliably be applied to the types of injuries at issue. And his opinion that

Plaintiffs [REDACTED]

[REDACTED], is irrelevant, prejudicial, and unreliable.

I. Dr. Bithoney's Opinion About General Causation Is Unreliable

In order to establish causation in a toxic-tort case, the plaintiff must establish general causation—that is, that the toxic substance in question is capable of causing the specific injury alleged by the plaintiff. *See Powell-Murphy v. Revitalizing Auto Communities Env't Response Tr.*, —Mich. App.—, No. 348690, 2020 WL 4722070, at *5 (Mich. Ct. App. Aug. 13, 2020); *Goetz v. Grand River Navigation Co.*, No. 16-cv-14489, 2018 WL 4030758, at *3 (E.D Mich. Aug. 23, 2018) (under Michigan law, “the issue is whether the chemicals were capable of causing the victim’s medical conditions”).

Here, Plaintiffs claim that they developed [REDACTED]

[REDACTED] as a result of their exposure to Flint’s water: [REDACTED]

[REDACTED] Report (E.S.) 7; Report (A.T.) 6; Report (R.V.) 6; Report (D.W.) 8. Dr. Bithoney opines that lead exposure is capable of causing [REDACTED], but his opinions are not grounded in a reliable methodology.

Dr. Bithoney presents no scientific evidence that lead exposure is capable of causing either [REDACTED] or [REDACTED] (both of which are clinical conditions requiring formal diagnoses), at any level of exposure, [REDACTED]. Of the various studies Dr. Bithoney cites, not

a single one addressed whether there is an association (let alone causation) between lead exposure and a diagnosis of [REDACTED] or [REDACTED].

At best, those studies suggest associations between lead exposure and certain types of cognitive or behavioral effects, none of which are sufficient to support a diagnosis of [REDACTED] or [REDACTED]. For example, Dr. Bithoney cites studies suggesting an association between lead exposure and lower IQ scores,² poorer performance on arithmetic and reading tests,³ and certain types of teacher-reported behaviors,⁴ but none examined whether there was any causal relationship between lead exposure and a diagnosis of either [REDACTED] or [REDACTED]. Dr. Bithoney also does not explain how the specific cognitive effects observed in these studies relate to an actual diagnosis of [REDACTED] or [REDACTED].

² Ex. 20, Joel Schwartz, *Low-Level Lead Exposure and Children IQ: A Meta-Analysis and Search for a Threshold*, 65 Env't Rsch. 42, 48 (1994) (Schwartz) (reporting that an increase in blood lead levels from 10 µg/dL to 20 µg/dL was associated with an estimated 2.6 point decrease in IQ, but not discussing any association with [REDACTED]); Marek Jakubowski, *Low-Level Environmental Lead Exposure and Intellectual Impairment in Children—The Current Concepts of Risk Assessment*, 24 Int'l J. of Occupational Med. & Env't Health 1, 6 (2010) (estimating that an increase in blood lead levels of 1.2 µg/dL could result in a 1 point decrease in IQ).

³ Ex. 22, Bruce P. Lanphear et al., *Cognitive Deficits Associated with Blood Lead Concentrations <10 µg/dL in US Children and Adolescents*, 115 Pub. Health Reps. 521, 528 (2000) (Lanphear) (reporting an association between lead exposure and four measures of intelligence at blood lead levels above 10 µg/dL).

⁴ Ex. 23, Lisa M. Chiodo et al., *Neurodevelopmental Effects of Postnatal Lead Exposure at Very Low Levels*, 26 Neurotoxicology & Teratology 359 (2004) (discussing increased incidence of teacher-reported “withdrawn behavior”).

██████████. Dr. Bithoney’s claim that lead can cause ██████████ or ██████████ overstates the adverse effects associated with lead exposure in the studies that he cites. When, as here, there is “too great an analytical gap between the data and the opinion proffered,” those opinions should be excluded. *Nelson*, 243 F.3d at 254 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Dr. Bithoney’s opinion that there is a causal relationship between lead exposure and ██████████ also lacks an adequate scientific basis. In support of his opinion, Dr. Bithoney cites just two studies—Ex. 23, Lisa Chiodo et al., *Neurodevelopmental Effects of Postnatal Lead Exposure at Very Low Levels*, 26 *Neurotoxicology & Teratology* 359 (2004) (Chiodo); and Ex. 21, Joseph Braun et al., *Exposures to Environmental Toxicants* ██████████ ██████████ *in US Children*, 114 *Env’t Health Perspectives* 12 (2006) (Braun). At best, the studies show an association between lead exposure and ██████████. An association, however, “does not mean there is a cause and effect relationship.” *Nelson*, 243 F.3d at 253; *In re Aredia & Zometa Prods. Liab. Litig.*, 483 F. App’x 182, 187 (6th Cir. 2012); *In re Dow Corning Corp.*, 541 B.R. 643, 651-52 (E.D. Mich. 2015) (excluding expert’s opinion based on an “association,” not causation, between silicone breast implants and autoimmune disease because testimony concerning an “association” amounted to “unsupported speculation”).

The Chiodo study did not examine the relationship between lead exposure and [REDACTED], but rather the relationship between lead exposure and teacher-reported [REDACTED]. Ex. 23, Chiodo 362. Such an association does not support a causal relationship between lead exposure and a clinical diagnosis of [REDACTED]. *Rochkind v. Stevenson*, 164 A.3d 254, 262 (Md. 2017) (“In equating [REDACTED] with a clinical [REDACTED] diagnosis, Dr. Hall-Carrington painted an inaccurate picture of the scientific research regarding lead poisoning—she overstated the known effects of lead exposure.”).

As for the Braun study, although the contributors to that study examined the relationship between lead exposure and the actual prevalence of [REDACTED], the study had two significant limitations. First, it found a statistically significant association only when individuals with certain levels of lead exposure were compared to one another. Specifically, to study the relationship between exposure and the prevalence of [REDACTED], the authors divided the population into quintiles based on their blood lead levels and compared the relative prevalence of [REDACTED] in the different groups. Ex. 21, Braun 1906. Although the authors found an association between lead exposure and [REDACTED], that association was statistically significant only when the first quintile was compared to the fifth quintile. *Id* at 1907. Thus, the study did not suggest that any increase in lead exposure resulted in an increased risk of [REDACTED], but rather that

there appeared to be an increased risk when an individual's blood lead level increased from below 0.7 µg/dL to above 2.0 µg/dL.⁵

Second, even with respect to the narrow association observed, the authors noted that the cross-sectional nature of the study prevented them from drawing any inferences about whether the relationship was causal.⁶ Ex. 21, Braun 1908. In other words, because it was a cross-sectional study, the authors could not tell from the data whether lead exposure was causing [REDACTED], or instead, whether [REDACTED] caused children with [REDACTED] to be exposed to higher amounts of lead.

Dr. Bithoney also fails to address the significant body of existing research suggesting that the relationship between lead exposure and [REDACTED] is too attenuated to be causal. In the most recent systematic review of the studies conducted to date,

⁵ Even if this single study were sufficient to establish a causal relationship, there is still no evidence that [REDACTED] as a result of the Flint water crisis, much less that Flint's water caused [REDACTED]. Dep. 126:3-19, 238:20-239:1.

⁶ In a cross-sectional study, "[t]he presence or absence of disease and the presence or absence of other variables are determined in each member of the study population or in a representative sample at one particular time." 3 David L. Faigman, *Modern Scientific Evidence: The Law and Science of Expert Testimony* ch. 23, App'x A (2020). In such a study, "because both exposure and disease are determined in an individual at the same point in time, it is not possible to establish . . . that the exposure preceded the disease, which would be necessary for drawing any causal inference." Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 560-61 (3d ed. 2011) (Fed. Jud. Ctr., *Reference Manual*).

the researchers stopped short of finding a causal relationship. They concluded that, while there was evidence of an association between lead exposure and [REDACTED], “additional data is needed to fully ascertain the nature of the relationship.” Ex. 24, Gabriele Donzelli et al., *The Association Between Lead and [REDACTED]*, [REDACTED]: *A Systematic Review*, 16 Int’l J. Env’t Rsch. & Pub. Health 382 (2019) at 11.

Significantly, two additional studies have been published since the Donzelli study, and neither found a significant relationship between lead exposure and [REDACTED]. See Ex. 25, Mireille Desrochers-Couture et al., *Association Between Early Lead Exposure and [REDACTED] in Adolescence: A Development Cascade*, 178 Env’t Rsch. 1, 11 (2020) (“No significant association was observed between child blood Pb concentrations and adolescent outcomes nor between adolescent blood Pb concentrations and [REDACTED] [REDACTED]”); Ex. 27, Yanfen Lin et al., *Blood Lead, Bone Lead and Child [REDACTED] Behavior*, 659 Sci. Total Env’t 161 (2019) at 7 (“After adjusting for potential confounders . . . no significant association was found between blood lead levels and any of child [REDACTED] symptoms and comorbidities.”).

Dr. Bithoney does not take those studies into account at all. His failure to do so casts significant doubt on the reliability of his causal claims and warrants their exclusion. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 799-800 (3d Cir. 2017) (explaining that experts' failure to address contrary studies can reveal an inconsistent application of methodology and thus warrant exclusion of their testimony); *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 475 (1st Cir. 2016) (expert's "complete unwillingness to engage with the conflicting studies . . . made it impossible for the district court to ensure that her opinion was actually based on scientifically reliable evidence and, correspondingly, that it comported with Rule 702").

Finally, the research casting doubt on the causal relationship between lead exposure and [REDACTED] is consistent with the testimony of Plaintiffs' own expert on general causation, Dr. Joseph Graziano. As Dr. Graziano testified at his deposition, the scientific literature has *not* established a causal link between lead exposure and any adverse health effects other than intelligence. Ex. 34, Graziano Dep. 139:14-140:24. When it comes to health effects other than intelligence, which would include [REDACTED], Dr. Graziano testified that the literature is merely "suggestive." *Id.*

II. Dr. Bithoney's Specific-Causation Opinion Is Unreliable

To prove specific causation in a toxic-tort case under Michigan law, a plaintiff must make the following three-part showing:

- **Exposure.** The plaintiff must prove that he or she actually “was exposed to the toxic substance.” *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 677 (6th Cir. 2011); *see Powell-Murphy*, 2020 WL 4722070, at *5 (plaintiff must show “that he or she was in fact exposed to the toxin at issue”).
- **Exposure Level.** The plaintiff must prove that his or her “level of exposure was sufficient to induce the complained-of medical condition.” *Pluck*, 640 F.3d at 677; *see Powell-Murphy*, 2020 WL 4722070, at *5 (plaintiffs must provide evidence of “specific exposure level” showing that it was “toxic and harmful”).
- **Factual Causation.** The plaintiff must prove that his or her exposure to the toxic substance actually “did cause[] the plaintiff’s alleged injury,” *Pluck*, 640 F.3d at 677, employing a method that reliably “eliminat[es] [other] likely causes.” *Id.* at 678; *see Powell-Murphy*, 2020 WL 4722070, at *5 (plaintiffs must “exclud[e] other reasonably relevant potential causes” to show that the alleged exposure “more likely than not caused the plaintiff’s injury”) (internal quotation marks and emphasis omitted).

Put another way, the specific-causation inquiry encompasses several “plaintiff-specific questions,” including “was plaintiff exposed to the toxin”; “was plaintiff exposed to enough of the toxin to cause the alleged injury”; and “did the toxin in fact cause the injury.” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005).⁷

⁷ *McClain* is cited with approval in both *Powell-Murphy* and Justice Markman’s concurring opinion in *Lowery v. Enbridge Energy Ltd. Partnership*, 500 Mich. 1034 (2017), which was adopted by the Michigan Court of Appeals in *Powell-Murphy*.

Here, each Plaintiff must establish that, as a result of VNA's alleged negligence, (1) he or she was actually exposed to additional lead in Flint's drinking water, *Pluck*, 640 F.3d at 677; (2) that his or her "level of exposure was sufficient to induce the complained-of medical condition," *id.*; and (3) that lead exposure attributable to VNA's alleged negligence, as opposed to other "likely causes," actually did cause his or her injury, *id.* at 678.

Dr. Bithoney's opinions on all three requirements are unreliable. First, his opinion that Plaintiffs were exposed to elevated lead in their drinking water is not supported by sufficient facts or data, and his effort to quantify Plaintiffs' exposures by referring to their bone lead levels is unreliable. Second, he fails to offer a reliable opinion about the threshold dose of lead needed to cause Plaintiffs' claimed injuries, instead assuming that any exposure to lead is harmful. Third, he does not identify or rule out possible alternative causes of Plaintiffs' alleged injuries.

A. Dr. Bithoney Failed To Conduct A Reliable And Sufficient Exposure Assessment

"A causation expert in a toxic tort case must always support his opinion with a reliable dose assessment." *Hendrian v. Safety-Kleen Sys., Inc.*, No. 08-cv-14371, 2014 WL 12658970, at *2 (E.D. Mich. Jan. 23, 2014); *see Pluck*, 640 F.3d at 677 (excluding specific-causation expert because expert failed to reliably estimate the

See Powell-Murphy, 2020 WL 4722070, at *5; *Lowery*, 500 Mich. at 1043, 1045 (Markman, J., concurring).

plaintiff's exposure to toxin). Here, Dr. Bithoney did not support his opinion with a dose assessment and therefore his opinion lacks a reliable scientific and legal basis.

1. Dr. Bithoney Lacked A Sufficient Factual Basis For His Conclusion That Plaintiffs Were Exposed To Elevated Levels Of Lead In Drinking Water

Dr. Bithoney asserts that all four Plaintiffs were exposed to additional lead in their tap water during the water crisis. *See, e.g.*, Report (E.S.) 5, 12-13; Report (A.T.) 5, 11-12; Report (R.V.) 4, 12; Report (D.W.) 3, 12. But Dr. Bithoney lacks a reliable basis for that conclusion. He does not consider important facts bearing on whether water lead levels at Plaintiffs' homes likely were elevated. And he does not attempt to quantify the supposed exposure.

a. Dr. Bithoney Did Not Reliably Assess The Facts About Specific Plaintiffs

Dr. Bithoney acknowledged at his deposition that he had no data showing the amount of lead in Plaintiffs' residential tap water during the water crisis. *See, e.g.*, Dep. 122:7-10, 140:6-11, 159:16-21, 183:17-23, 196:4-8. The only water lead level test he could identify was one that E.S.'s mother told him she performed "[a]t some point late in 2015 or early 2016." Report (E.S.) 3. According to Dr. Bithoney, she said that the test "turned red," which she understood to mean that there was lead in the water. *Id.*; *see* Dep. 121:14-123:6.⁸ Dr. Bithoney described the test as

⁸ Although Dr. Bithoney states in his report that E.S.'s mother described the test as a "home *lead* test kit" and that the results indicated the presence of "lead," Report

“qualitative,” meaning that it did not show how much lead was in the water. Dep. 122:19-123:5. And he has no testing information at all for the other three Plaintiffs.

Even assuming that this test was a test for lead, it does not show that the amount of lead in E.S.’s home increased after the change in water source, because lead may have been present in E.S.’s drinking water before the City began using water from the Flint River. Moreover, a positive lead test in E.S.’s home does not mean that there was lead in the other three Plaintiffs’ drinking water. The lack of reliable information about the concentration of lead in Plaintiffs’ drinking water makes it impossible for Dr. Bithoney to render a reliable opinion about either the fact of their exposure or the degree of their exposure. *See Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 70 (D. Mass. 2000) (rejecting expert causation testimony

(E.S.) 3 (emphasis added), at her deposition E.S.’s mother described the kit in more general terms, referring to it as a “home *water* test kit,” Ex. 15, Wheeler Dep. 180:7-182:1. She also testified that the results (“turn[ing] red”) indicated that the water was “bad”; she did not say that the results meant that the water contained lead. *Id.* Dr. Bithoney testified that he did not ask E.S. to send him the actual test results or the test kit materials. In fact, Dr. Bithoney did not have any information about the manufacturer, brand, or type of test kit that might enable him to confirm E.S.’s mother’s recollection. Dep. 122:15-123:5. He just took her word for it. By so doing, he failed to “employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,” which is a hallmark of unreliable expert testimony. *Kumho*, 526 U.S. at 152; *see State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1039 (N.D. Ind. 2013) (“Dr. Wood’s own testimony was that she accepted the reports she received from [the defendant] and did nothing additional to research the sources of the information, how the data was compiled, or verify the reliability of the data. This problem . . . renders Dr. Wood’s opinion unreliable.”).

because expert failed to determine the actual concentration of the toxin emitted and thus was unable to estimate the dose to which the plaintiff could have been exposed); *Bland v. Verizon Wireless (VAW) L.L.C.*, No. 06-cv-00008, 2007 WL 5681791, at *9 (S.D. Iowa Aug. 9, 2007), *aff'd*, 538 F.3d 893 (8th Cir. 2008) (holding that doctor's causation testimony was inadmissible "because the doctor did not determine the amount of the agent emitted [by the exposure source], and therefore she could not determine or estimate the amount . . . to which the plaintiff was actually or probably exposed").

Without reliable test results, Dr. Bithoney attempts to rely on statements from parents. He states that "each parent I spoke with reported that the water in their home in 2014 and 2015 was malodorous and/or discolored." Report (E.S.) 4. According to Dr. Bithoney, this "suggests"—"but does not prove"—that their water was [lead] tainted as well." *Id.* That is the problem; these statements provide no proof of lead exposure, and without that, Dr. Bithoney cannot show causation. Further, Dr. Bithoney does not provide any scientific evidence of an association between water discoloration or odor and elevated lead levels. As Dr. Bithoney repeatedly acknowledged, he is not an expert on water systems, plumbing, or pipes. Dep. 115:23-116:4, 226:12-24, 230:16-231:4. Accordingly, this observation does not reliably support Dr. Bithoney's opinion that the water lead levels in Plaintiffs' homes were elevated.

Dr. Bithoney also failed to investigate whether Plaintiffs' homes had lead service lines, even though this fact is critical to evaluating the likelihood that the lead in their drinking water was elevated. As VNA's expert toxicologist, Brent Finley, explains, lead service lines are the most significant source of lead contamination in tap water. Ex. 8, Finley Report 27. Dr. Bithoney likewise recognizes that the presence of lead service lines was a significant factor affecting the water lead levels of Flint homes. During his deposition, he repeatedly cited data about the estimated number of lead service lines in Flint as evidence of widespread lead contamination. Dep. 96:3-97:9.

Yet Dr. Bithoney made no effort to determine the composition of Plaintiffs' service lines. Dep. 113:8-10, 115:6-116:4, 140:12-17. That is significant because all four Plaintiffs had *copper* services lines, not lead. Ex. 8, Finley Report 37 (E.S.); *id.* at 47 (A.T.); *id.* at 54 (R.V.); *id.* at 60 (D.W.). Researchers have estimated that during the water crisis, the median lead level of homes with copper service lines was approximately one-third of the median lead level of homes with lead service lines. *Id.* at 27. For example, in August 2015, Virginia Tech's Flint Water Study sampled 228 homes with copper service lines and found that the majority (115) had water lead levels below the detection limit of 1 part per billion (ppb). *Id.* at 28. So the fact that Plaintiffs' homes had copper service lines seriously undercuts Dr. Bithoney's claim of lead exposure.

Further, Dr. Bithoney failed to adequately investigate whether Plaintiffs were exposed to lead from sources other than Flint’s water, such as lead paint, lead dust, or baby food. As he conceded, “[i]t is possible [that] the [plaintiffs] had other sources of lead intoxication.” Dep. 213:9-21; *see id.* at 225:19-226:6. All he did to investigate potential alternative sources was to ask Plaintiffs’ parents during a telephone call whether they knew of any alternative sources of exposure. *Id.* at 207:14-208:8. That is not an adequate investigation—especially given Plaintiffs’ low blood lead levels and Dr. Bithoney’s acknowledgment that lead is ubiquitous. *Id.* at 36:23-37:9, 286:10-287:15; *see* Fed. Jud. Ctr., *Reference Manual* 522 (explaining that the “critical first step” in a reliable exposure assessment requires that the expert account for “all conceivable pathways” of exposure); *Palmer v. Asarco Inc.*, No. 03-cv-0498, 2007 WL 2298422, at *8 (N.D. Okla. Aug. 6, 2007) (excluding expert’s opinion that low-level lead exposure caused the plaintiff’s alleged cognitive deficits where expert’s “report [was] completely devoid of any evidence that he performed a differential diagnosis . . . and his deposition provide[d] few specifics about his analytical process”). Plaintiffs’ parents cannot be expected to know about and report on Plaintiffs’ exposures to lead paint, lead dust, and lead in soil. Nor could they have been expected to know that baby food is a source of lead (as well as other heavy metals that can cause neurocognitive effects).

An expert who simply adopts assumptions or data provided by a litigant without independent verification “goes beyond relying on facts or data and instead cloaks unexamined assumptions in the authority of expert analysis.” *Ask Chems., LP v. Computer Packages, Inc.*, 593 F. App’x 506, 510 (6th Cir. 2014). Accordingly, “[w]hen an expert’s proffered opinion merely parrots information provided to him by a party, that opinion is generally excluded.” *Id.* at 511 (quoting *King-Indiana Forge, Inc. v. Millennium Forge, Inc.*, No. 07-cv-00341, 2009 WL 3187685, at *2 (S.D. Ind. Sept. 29, 2009)); *see, e.g., Ellipsis, Inc. v. Color Works, Inc.*, 428 F. Supp. 2d 752, 760-61 (W.D. Tenn. 2006) (excluding testimony of expert because opinion was based on unverified data provided by the party who retained him). Because Dr. Bithoney did not independently investigate any alternative sources of lead, choosing instead to rely on general statements from Plaintiffs’ parents, his opinion that Plaintiffs were exposed to lead through Flint’s water is unreliable and should be excluded.

b. The Population-Level Studies And Data That Dr. Bithoney Cites Do Not Support His Opinion That Plaintiffs Were Exposed To Elevated Levels Of Lead In Drinking Water

Unable to marshal plaintiff-specific evidence that Plaintiffs’ drinking water had elevated lead levels, Dr. Bithoney cites population-level studies of Flint that suggested that the levels of lead in Flint’s water increased after the change in water sources. These studies do not show that every home—or even most homes—in Flint

experienced elevated water lead levels. They therefore do not provide a reliable basis for Dr. Bithoney's opinion that every Plaintiff was exposed to elevated amounts of lead in drinking water after the switch to Flint River water.

As both the Sixth Circuit and judges in this District have recognized, population-level studies showing that a toxin was present in the environment are insufficient to support the opinion that a particular person was exposed to that toxin. *Nelson*, 243 F.3d at 252-53 (evidence that toxins "were present in the environment in excess of allowable limits and [that] plaintiffs lived and worked in the area" was insufficient to establish that the plaintiffs "were in fact exposed" to the toxins); *Hendrian*, 2014 WL 12658970, at *4 (excluding expert testimony that presumed that the plaintiffs were exposed to toxic levels of benzene simply because they worked at a facility containing products with benzene in them); *Cowan v. Arkema, Inc.*, No. 04-cv-71143, 2007 WL 3203249, at *3 (E.D. Mich. Oct. 31, 2007) (evidence that the plaintiffs lived within the area exposed to a chemical release did not establish that they were exposed at levels sufficient to cause injury). That principle applies here. None of the studies Dr. Bithoney cites shows that any Plaintiff was exposed to lead through Flint's water.

First, Dr. Bithoney cites a study conducted by Virginia Tech University that found that 40% of the homes that the researchers tested had lead levels greater than 5 ppb and that 17% of the homes had water lead levels greater than 15 ppb. Report

(E.S.) 4 (citing Jeffrey Parks & Anurag Mantha, *Lead Testing Results for Water Sampled by Residents*, Flint Water Study (Sept. 2015), <https://bit.ly/3eQkEPK>); *see* Report (A.T.) 4; Report (R.V.) 4; Report (D.W.) 4. This study—which included many homes that had lead service lines—provides no information about the amount of lead in Plaintiffs’ water. The study also does not show that the observed water lead levels represented a significant increase above water lead levels in prior years. As VNA’s expert toxicologist, Dr. Finley, explains, water lead levels above 15 ppb were common in Flint even before the water crisis. Ex. 8, Finley Report 17. According to the best available estimates, at least 10% of Flint homes had water lead levels higher than 15 ppb in each of the four years preceding the water crisis. *Id.*

Next, Dr. Bithoney cites a media report stating that the City of Flint’s FAST Start pipe-replacement program had estimated that the service lines of approximately 29,100 homes in Flint could contain segments of lead pipe requiring replacement. Report (E.S.) 4; Report (A.T.) 4; Report (R.V.) 4; Report (D.W.) 4. Dr. Bithoney conceded that he did not review the underlying FAST Start data to determine whether that estimate was accurate, but instead relied on the newspaper article cited in his report as evidence of wide-spread lead contamination. Dep. 144:2-23. So Dr. Bithoney did not do the work needed to reliably conclude that Plaintiffs were exposed to lead through the drinking water.

Even if Dr. Bithoney's assumption that all of these 29,100 homes had lead service lines were correct, he conceded that he did not know whether Plaintiffs lived in one of these 29,100 homes. Dep. 140:18-24, 144:24-145:6. And there is evidence showing that they did not: Publicly available information from the FAST Start program confirms that Plaintiffs' homes did not have lead service lines. Ex. 8, Finley Report 30 (explaining that the FAST Start data establish that none of Plaintiffs' homes had lead service lines); Ex. 31, Edwards Decl. ¶¶ 7-8; Ex. 30, Phaneuf Decl. ¶¶ 13-14.

Finally, Dr. Bithoney contends that Plaintiffs must have been exposed to toxic levels of lead from Flint's water because Flint children have had a higher incidence of learning disabilities since the water crisis. In support of this conclusion, Dr. Bithoney cites a 60 Minutes segment about Flint that discussed the Flint Registry. The Flint Registry is a program that provides preliminary neurodevelopmental assessments to Flint children to determine whether they have potential learning or developmental disorders. Flint Registry, *About*, <https://www.flintregistry.org/about/> (last visited May 4, 2021). During this segment, the reporter states that the Flint Registry shared its "preliminary findings," which 60 Minutes summarized as follows: "Before the crisis, about 15% of the kids in Flint required special education services. But of the 174 children who went through the extensive neuro-exams, specialists determined that 80% will require help for a language, learning or

intellectual disorder.” Ex. 17, Sharyn Alfonsi, *Early Results from 174 Flint Children Exposed to Lead During Water Crisis Shows 80% of Them Will Require Special Education Services*, CBS News (Mar. 15, 2020) at 5 (60 Minutes Report). Although 60 Minutes did not provide any additional information concerning these “preliminary findings,” Dr. Bithoney accepts them as fact without making any attempt to verify them. Then Dr. Bithoney cites these “findings” as proof that there was increased lead in Flint’s water because, according to him, lead is associated with language, learning, and intellectual disorders.

Dr. Bithoney’s reliance on a 60 Minutes story underscores that he failed to use a reliable methodology and failed to base his conclusions on reliable data. He relied on a news story, rather than the type of scientific studies and data that others in his field would use. *See Ask Chems., LP*, 593 F. App’x at 510 (holding that an expert may rely on otherwise inadmissible hearsay evidence in forming his opinion “if the facts and data upon which he relies are of a type reasonably relied upon by experts in his field”) (quoting *Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1182 (8th Cir. 1997)). This is particularly true because the findings are expressly reported as “preliminary,” have not been peer-reviewed (or even formally published), and the news report does not provide any information about the methodology employed. Ex. 17, 60 Minutes Report 5.

Further, the news report does not show the necessary causal connection. As the Sixth Circuit has recognized, an apparent temporal relationship between exposure to a toxin and the onset of certain symptoms associated with such exposures does not establish a causal relationship. *Rolen v. Hansen Beverage Co.*, 193 F. App'x 468, 473 (6th Cir. 2006) (“Expert opinions based upon nothing more than the logical fallacy of *post hoc ergo propter hoc* typically do not pass muster under *Daubert*.”); *Downs v. Perstorp Components, Inc.*, 26 F. App'x 472, 473-76 (6th Cir. 2002) (excluding expert methodology of “reasoning backwards” from the presence of a condition to the cause of that condition without any actual exposure assessment). There is no way to know whether children whom the Flint Registry assessed as potentially needing “help for a language, learning or intellectual disorder” would have received the same assessment *before* the crisis, because they were not evaluated until after the crisis. Thus, Dr. Bithoney’s inference that all of these children must have been exposed to harmful amounts of lead in the water is unscientific and unreliable.

2. Plaintiffs’ Blood Lead Levels Do Not Support Dr. Bithoney’s Exposure Assessment

There is a broad scientific consensus that blood lead testing (preferably from a venous blood draw) is the best means of assessing an individual’s lead exposure. For example, the CDC states that “[b]lood lead measurement is the preferred method of evaluating lead exposure and its human health effects. [Blood lead levels] reflect

both recent intake and equilibration with stored lead in other tissues, particularly in the skeleton.” Ex. 8, Finley Report 80 (citing CDC Nat’l Biomonitoring Program, *Biomonitoring Summary for Lead* (2017)). Dr. Bithoney admits that assessment of blood lead levels is the “standard of care” and the “gold standard” when evaluating patients for lead exposure in clinical practice. Dep. 66:6-10.

The problem for Dr. Bithoney is that Plaintiffs’ blood lead levels were [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]


[REDACTED]

Perhaps because Plaintiffs’ blood lead levels [REDACTED], Dr. Bithoney tries to undermine them. He suggests that the blood lead level tests do not accurately reflect Plaintiffs’ blood lead levels during the water crisis. Dep. 204:13-17, 210:6-24. His

reasoning is that lead constantly is being eliminated from the body at an average rate of approximately 50% percent every 10 days in children,⁹ so a child's blood lead level always will be lower than it was the level of the previous day. Report (E.S.) 9-10; Report (A.T.) 6-8; Report (R.V.) 6-8; Report (D.W.) 6-8.

The flaw in that reasoning is that new exposures are occurring at the same time that the body is eliminating lead from past exposures. Dr. Bithoney admits that. Dep. 36:23-37:9, 117:15-119:8, 207:6-13. His opinion that the blood lead levels underestimated lead exposure assumes that a person is eliminating lead from past exposures faster than he or she is ingesting lead from new exposures. But he never tried to check that. And he never looked at other exposures, such as from soil, paint, dust, air, baby food, or the other "fairly typical" exposure sources. *Id.* at 36:20-

⁹ Dr. Bithoney's opinion that the half-life of lead in children is just 10 days is wildly inaccurate. As explained in VNA's motion to exclude Plaintiffs' bone lead expert, Dr. Aaron Specht, studies have shown that the actual half-life of lead in children is far longer, ranging from eight months to several years. Thus, if Plaintiffs' blood lead levels were significantly elevated as a result of exposure to lead, between February 2015 (when VNA began working in Flint) and October 2015 (when Flint switched back to Detroit water), then they would still have been elevated in early 2016.



37:10, 117:15-119:8, 207:6-13, 225:19-226:6. So his opinion that Plaintiffs' blood lead levels [REDACTED] is speculative and unreliable.

3. Plaintiffs' Bone Lead Levels Do Not Provide Reliable Information About Plaintiffs' Exposure To Lead In Flint's Water During The Water Crisis

Without support from the blood lead tests, Dr. Bithoney relies on *bone* lead tests. He says those tests show that Plaintiffs experienced [REDACTED] [REDACTED] Report (E.S.) 5; Report (A.T.) 4; Report (R.V.) 4; Report (D.W.) 3. He also opines that Plaintiffs' bone lead levels are [REDACTED] [REDACTED] Report (E.S.) 5; Report (A.T.) 4; Report (R.V.) 4; Report (D.W.) 3.

These opinions are unreliable and should be excluded for several reasons. First, the novel methodology used to measure Plaintiffs' bone lead levels has not been validated and does not produce accurate measurements in children. Second, even if the bone lead readings are accurate, they cannot show the source of the lead exposure. Finally, because bone lead levels reflect cumulative lead exposure over a lifetime, Plaintiffs' bone lead levels cannot be used to determine the timing of the exposure.

a. The pXRF Methodology Does Not Accurately Measure Bone Lead In Children

As explained in VNA's motion to exclude the opinions and testimony of Dr. Aaron Specht, the methodology employed to measure Plaintiffs' bone lead levels is

not reliable when used on children. In fact, Dr. Specht's own research has found just the opposite—that "Portable X-Ray Florescence" (pXRF) does not produce accurate measurements of children's bone lead levels. Dr. Bithoney's opinions thus are inadmissible because they rest on an unreliable testing methodology.

b. The Bone-Lead Measurements Do Not Provide A Reliable Basis For Dr. Bithoney's Opinion That Plaintiffs Were Exposed To A Harmful Amount Of Lead

Further, Dr. Bithoney's conclusions that Plaintiffs' bone lead levels demonstrated [REDACTED], Report (E.S.) 5, is inadmissible because reliable data regarding typical or baseline levels of bone lead in children do not exist. In other words, because no one has determined the bone lead level of a typical child with average exposure, Dr. Bithoney cannot compare Plaintiffs' bone lead levels to those averages in order to assess whether and how significantly Plaintiffs' bone lead levels exceed the norm. Absent some established benchmark for comparison, Dr. Bithoney's opinions regarding the significance or relative amount of Plaintiffs' exposures lack any reliable scientific foundation.

In an apparent attempt to provide some point of comparison, Dr. Bithoney initially stated in his reports that "[l]evels of > 10 mcg per gram of bone [lead] indicate persistent ongoing exposure" and that "[b]one [lead] levels of > 20 mcg per gram of bone mineral indicate intense exposure." Report (E.S.) 5. At his deposition,

however, Dr. Bithoney withdrew his opinions regarding these supposed benchmarks. Dep. 284:16-21. As Dr. Bithoney testified, he was relying entirely on statements Dr. Specht initially included in his reports but later disavowed. *Id.* at 283:17-284:19.

The only other point of comparison Dr. Bithoney cites for his opinion that Plaintiffs' bone lead levels demonstrated [REDACTED] exposure to lead is a study reporting the bone lead levels of children in Canada. Report (E.S.) 5 (citing F.E. McNeil et al., *The Decrease in Population Bone Lead Levels in Canada Between 1993 and 2010 as Assessed by In Vivo XRF*, 39 *Physiological Measurement*, no. 015005 (2018)). As explained in VNA's motion to exclude Dr. Specht's testimony, this study does not provide an adequate basis for comparison because, *inter alia*, it did not assess bone lead levels using a pXRF machine. Instead, the study population's bone lead levels were assessed using a KXRF machine. As Dr. Specht has found on multiple occasions, KXRF bone lead measurements and pXRF bone lead measurements are not correlated in children. Dr. Specht attributed the lack of correlation in children to their lower bone density and thicker fatty tissue, which affects the accuracy of the pXRF's measurements. Thus, in comparing Plaintiffs' bone lead levels to those of the children in the Canada study, Dr. Bithoney engaged in an apples-to-oranges comparison. *See Lee-Bolton v. Koppers, Inc.*, 319 F.R.D. 346, 374-76 (N.D. Fla. 2017) (rejecting expert opinion based on "screening"

method of quantifying exposure that overestimated exposure and could not be validated against the standard method used to assess exposure to the substance at issue); *State Farm*, 980 F. Supp. 2d at 1039 (expert's "analysis suffered from a reliability flaw because she had not confirmed that her analysis was comparing apples to apples rather than apples to oranges"). Because the Canada study does not support Dr. Bithoney's opinion that Plaintiffs were exposed to a harmful amount of lead, that opinion is unreliable and should be excluded.

c. The Bone-Lead Measurements Cannot Show That Plaintiffs Suffered Lead Exposure Resulting From The Water Crisis

Finally, Plaintiffs' bone lead measurements cannot show either the source or the timing of Plaintiffs' alleged lead exposures. Dr. Specht admitted that bone lead measurements cannot differentiate among the possible sources of lead exposure over a subject's lifetime. Ex. 10, Specht Report 3-4; Ex. 14, Specht Dep. 210:2-11. Dr. Bithoney nevertheless contends that Plaintiffs' bone lead levels demonstrate [REDACTED] exposure from Flint's tap water during the water crisis. *E.g.*, Report (E.S.) 5. To support this assertion, Dr. Bithoney first attempts to estimate Plaintiffs' bone lead levels during the water crisis by extrapolating backwards from their August 2019 bone lead levels using the half-life of bone lead. Assuming a two-year half-life, Dr. Bithoney opines that Plaintiffs' bone lead levels in August 2017 must have been twice as high as they were in August 2019 and four

times as high in August 2015. Dep. 202:2-205:8. Thus, for example, according to Dr. Bithoney, E.S.'s bone lead level of [REDACTED] in August 2019 implies a bone lead level of approximately [REDACTED] in August 2017 and [REDACTED] in August 2015. Dep. 202:12-24. Next, Dr. Bithoney asserts that all of Plaintiffs' bone lead had to be attributable to Flint's water because there was "no evidence" and "no reason to believe that there [was] another source for [Plaintiffs'] lead intoxication." *Id.* at 396:1-23. That methodology suffers from at least three major flaws.

First, the half-life of lead in the bones of children is not known, Dep. 338:13-340:21, and Dr. Bithoney's estimate that it is approximately two years is not reliable. As Dr. Finley explained, Dr. Bithoney's two-year estimate (which is an order of magnitude lower than the half-life observed in adults) is based on studies suggesting that children replace approximately 50% of their cortical bone every two years. Ex. 8, Finley Report 98. However, Dr. Bithoney does not identify any scientific support for his assumption that bone lead is released at the same rate that bone is replaced.

Second, Dr. Bithoney's calculation of Plaintiffs' bone lead levels during the water crisis is not reliable. Dr. Bithoney's methodology ignores that Plaintiffs continued to be exposed to lead from a variety of sources over the four years between the water crisis and the dates on which their bone lead levels were measured. For example, the fact that E.S.'s bone lead level was [REDACTED] in August 2019 does not

mean that it was [REDACTED] in August 2015. E.S.'s bone lead level just as likely could have been [REDACTED] in August 2015, and the levels observed in August 2019 just as likely could have been the result of cumulative daily exposures to lead in air, dust, soil, and water in the four years after the crisis.

Finally, Dr. Bithoney's backwards extrapolations would indicate, at best, that Plaintiffs had a particular level of lead in their bones during the water crisis, but still would not say anything about the source of that lead. Dr. Bithoney attempts to address this hole in his opinion by stating that he did not have evidence that Plaintiffs were exposed to any alternative source of lead and concluding that their bone lead levels therefore must be attributable to lead in Flint's water. But Dr. Bithoney's assertion that there was "no other source," Dep. 212:23-213:8, cannot be reconciled with his recognition that lead is ubiquitous and that exposure from a variety of sources—*e.g.*, soil, dust, paint, air, or food—is unavoidable. *Id.* at 36:23-37:9, 207:6-13. Dr. Bithoney's statement that he "had no evidence" that Plaintiffs were exposed to lead from other sources is true only because he made no effort to investigate alternative exposure sources.

For all of those reasons, Dr. Bithoney's opinions based on Plaintiffs' bone lead levels are unreliable and unhelpful and therefore should be excluded.

B. Dr. Bithoney Does Not Provide Reliable Testimony About The Level Of Exposure Necessary To Cause Plaintiffs' Injuries

In addition to establishing the extent of the plaintiff's exposure to the toxin at issue, an expert opining on specific causation must present reliable evidence about the level of exposure necessary to cause the plaintiff's particular injuries. Dr. Bithoney's specific-causation opinion should be excluded because he does not provide reliable evidence that Plaintiffs' exposures were sufficient to cause their claimed injuries.

1. Dr. Bithoney Fails To Provide Any Evidence That Plaintiffs' Bone Lead Levels Were Sufficient To Cause Their Injuries

Plaintiffs' bone lead levels do not provide a basis for Dr. Bithoney's specific-causation opinions because they do not reliably demonstrate significant incremental lead exposure that can be attributed to the water crisis or to any alleged negligence on the part of VNA.

Dr. Bithoney provides no evidence that the degree of lead exposure associated with bone lead levels like Plaintiffs' is capable of causing their specific injuries. As the leading resource on scientific evidence explains, "[t]he dose metrics emerging from the exposure assessment need to match the dose metrics that are used to describe toxicity risks." Fed. Jud. Ctr., *Reference Manual* 533. Here, the dose metrics Dr. Bithoney relies on for his exposure assessments are Plaintiffs' *bone* lead levels, but all of the relevant studies, regulatory guidance, and even Dr. Bithoney's

own clinical practice, rely on *blood* lead levels to identify the health effects associated with lead exposure. As the CDC's Agency for Toxic Substance and Disease Registry (ATSDR) notes:

Studies conducted in children have relied heavily on [blood lead] as an exposure metric. Although bone or tooth [lead] measurements may be informative, few studies have been conducted in children. . . . An association between a health outcome and [bone lead] does not necessarily infer an association between the outcome and [blood lead] (or *vice versa*) as indicated by studies in which associations are not consistent for the two metrics.

ATSDR, *Toxicological Profile for Lead* 134 (2020), <https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>.

Dr. Bithoney does not identify a single study suggesting that Plaintiffs' bone lead levels are associated with any injuries, much less the particular injuries Plaintiffs allege that they sustained. Without some evidence that bone lead levels comparable to Plaintiffs' are associated with Plaintiffs' specific claimed conditions, Dr. Bithoney's opinion that Plaintiffs were exposed to sufficient lead to cause their injuries is unreliable. *Amorgianos v. Nat. R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 169 (E.D.N.Y. 2001), *aff'd*, 303 F.3d 256 (2d Cir. 2002) (explaining that the plaintiff's dose should be measured in the same way it is measured in the studies suggesting an association between toxin and adverse effects); *see Lee-Bolton*, 319 F.R.D. at 374-376 (rejecting expert opinion based on "screening" method of

quantifying exposure that overestimated exposure and could not be validated against the standard method used to assess exposure to the substance at issue).

2. Dr. Bithoney's "No Safe Level" Opinion Is Not Admissible

a. Courts Regularly Exclude As Unreliable Expert Testimony That Ignores The Relationship Between Dose And Toxicity

Dr. Bithoney attempts to support his opinion on causation by asserting that there is "no safe level" of lead exposure and that "[a]ny level of lead" is toxic. Report (E.S.) 9; Report (A.T.) 10; Report (R.V.) 10; Report (D.W.) 10. Courts have consistently rejected this type of "no safe dose" theory as inherently unreliable.

Dr. Bithoney's theory that any level of lead is capable of causing harm directly contradicts the fundamental tenet of toxicology that "the dose makes the poison." Fed. Jud. Ctr., *Reference Manual* 636. "[A]ll chemicals have thresholds of exposure that must be exceeded before the harms will occur." *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 849 (N.D. W. Va. 2013).

Lead is no exception. As VNA's expert toxicologist, Dr. Finley, explains, all persons are exposed to lead on a daily basis due to the presence of lead in the diet, drinking water, air, soils, and other media," yet there is "no evidence that all persons . . . have developed or are developing lead-related illnesses." Ex. 8, Finley Report 54.

Michigan law recognizes the critical importance of dose in determining whether a substance has caused a plaintiff's harm. Courts in toxic-tort cases in Michigan require plaintiffs to introduce "not simply proof of exposure to the substance, but proof of *enough* exposure to cause the plaintiff's specific illness." *Lowery*, 500 Mich. at 1043 (Markman, J., concurring) (quoting *McClain*, 401 F.3d at 1242) (emphasis added); see *Powell-Murphy*, 2020 WL 4722070, at *6 (adopting the causation framework described in Justice Markman's *Lowery* concurrence).

It is "well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff's symptoms." *Pluck*, 640 F.3d at 679 (applying Ohio law). Because "a substance may cause different harmful effects in different doses," "a substance may be harmful at a certain level of exposure but may not be sufficient to cause a particular adverse health effect." *Lowery*, 500 Mich. at 1044 (Markman, J., concurring). Dosage is "the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 11 (2003-2004) (Eaton, *Primer*) (cited in *Lowery*, 500 Mich. at 1043-44 (Markman, J., concurring)). Given the importance of dosage to the science of toxicology, "the expert who avoids or neglects this principle of toxic

torts without justification casts suspicion on the reliability of his methodology.” *McClain*, 401 F.3d at 1242.

The Sixth Circuit has consistently applied this principle. In *Nelson*, for example, the Sixth Circuit recognized that the reasoning and methodology underlying the opinion of an expert who makes no attempt to determine the dosage the plaintiffs received and simply assumes that it was sufficient to make them ill is inherently unreliable. 243 F.3d at 253. The Sixth Circuit similarly held in *Pluck* that it is “well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff’s symptoms.” 640 F.3d at 679.

Courts outside the Sixth Circuit have found similar “no safe dose” testimony to be unreliable and have excluded it. *See, e.g., McClain*, 401 F.3d at 1242-43 (holding that district court abused its discretion by not excluding the causation opinion of the plaintiff’s expert because his opinion that “any amount of [the product] is too much . . . clearly contradicts the principles of reliable methodology”); *Wills v. Amerada Hess Corp.*, 379 F.3d 32, 38, 48-50 (2d Cir. 2004) (affirming exclusion of expert testimony because expert had posited that “there is no safe level of exposure” rather than relying on a tested, accepted, dose-response methodology); *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 25 (D. Mass. 1995) (holding that expert opinion relying on the theory that any exposure is harmful regardless of dose

“fails all of the *Daubert* reliability factors”); *Adams*, 2007 WL 2219212, at *7 (holding that “the ‘no-safe-dose’ theory is not a reliable methodology”); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1165-66 (E.D. Wash. 2009) (“The use of the no safe level or linear ‘no threshold’ model for showing unreasonable risk ‘flies in the face of the toxicological law of dose-response, that is, that the dose makes the poison.’”). As these courts have noted, “no safe dose theories” are inherently suspect from a scientific standpoint because they ignore the toxicological principle of dose-response, which holds that all substances have some threshold level of exposure that must be exceeded to cause harm. *McClain*, 401 F.3d at 1242-43.

b. Dr. Bithoney’s Opinion That Any Exposure Is Sufficient To Cause Injury Is Unreliable

Dr. Bithoney’s opinion that any exposure to lead is harmful is unreliable by every measure. He does not demonstrate that his theory has “been tested,” that it has “been subjected to peer review and publication,” or that it “enjoys general acceptance in a relevant scientific community.” *Nelson*, 243 F.3d at 251 n.5. In fact, he points to no scientific determination anywhere that every lead exposure is associated with adverse health effects.

As support for his theory, Dr. Bithoney relies primarily on public health guidelines from the CDC and National Institutes of Health (NIH). *See, e.g.*, Report (E.S.) 10. However, none of these guidelines say that any amount of lead exposure is capable of causing harm. Rather, they provide that “[n]o safe blood lead level in

children *has been identified.*” Ex. 18, CDC, *Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations* 5 (June 7, 2012) (emphasis added); Ex. 19, NIH, *Lead and Your Health* 3 (2013) (“[T]he CDC has dropped the level of concern terminology since no safe blood lead level in children has been identified.”).

The fact that science has yet to identify a safe level of lead does not mean that none exists. Courts have noted that important distinction in excluding similar testimony. *See Comardelle v. Pa. Gen. Ins. Co.*, 76 F. Supp. 3d 628, 634 (E.D. La. 2015) (“Although there may be no known safe level of asbestos exposure, this does not support [the expert witness’s] leap to the conclusion that therefore every exposure . . . must have been a substantial contributing cause of [the plaintiff’s] mesothelioma.”); *Anderson v. Ford Motor Co.*, 950 F. Supp. 2d 1217, 1223 (D. Utah 2013) (same).

Second, as courts have consistently recognized, public-health guidelines concerning “safe” levels of exposure to a toxin are not useful for purposes of establishing causation. Because the purpose of such guidelines is to protect the general public from any harm, regulatory agencies typically set exposure thresholds at levels for which “there is no appreciable risk.” *Rhodes v. E.I. du Pont de Nemours & Co.*, 253 F.R.D. 365, 377-78 (S.D. W. Va. 2008). Put another way, regulatory levels and public-health guidelines tend to “overestimate potential toxicity levels for

nearly all individuals” based on various “protective, often ‘worst-case’ assumptions.” Eaton, *Primer* 34-35.

Whether a particular threshold is capable of causing harm from a regulatory perspective involves a “threshold of proof that is reasonably lower than that appropriate in tort law.” *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996); *see also Burst v. Shell Oil Co.*, No. 14-cv-109, 2015 WL 3755953, at *8 (E.D. La. June 16, 2015) (collecting cases about irrelevance of regulatory guidelines). For that reason, courts do not permit plaintiffs to prove causation by substituting regulatory standards for a toxicity threshold. *See, e.g., Sutura v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 664 (D. Mass. 1997) (rejecting regulatory standards as proof of causation because the purpose of regulatory standards is to “reduce public exposure to harmful substances” regardless of whether the level of exposure presents a likely—or even a reasonable—risk of harm); *O’Neal v. Dep’t of the Army*, 852 F. Supp. 327, 333 (M.D. Pa. 1994) (EPA risk assessments are “appropriate for regulatory purposes in which the goal is to be particularly cautious [but] overstate the *actual* risk and so, are inappropriate for use in determining whether medical monitoring should be instituted”).

In short, the regulatory guidelines lend no scientifically or legally valid support to Dr. Bithoney’s opinion that any amount of lead exposure is sufficient to cause harm.

3. Dr. Bithoney's Opinions About The Association Between Various Health Effects And Blood Lead Levels [REDACTED] Are Unreliable

Dr. Bithoney cites various studies suggesting that certain adverse effects associated with lead have been observed at “low levels” of exposure (*e.g.*, blood lead levels below [REDACTED]). These studies do not support Dr. Bithoney's specific-causation opinions for three reasons.

First, Dr. Bithoney expressly disavowed any reliance on Plaintiffs' blood lead levels for purposes of assessing the extent of their exposures to lead and whether those exposures could have caused their specific injuries. Dep. 204:13-17 (“The levels of lead in the blood . . . are meaningless to me.”); *see id.* at 233:22-234:3, 399:10-19. Instead, Dr. Bithoney's exposure assessments are based on Plaintiffs' *bone* lead levels. None of the studies Dr. Bithoney cites on the health effects associated with low blood lead levels say anything about how those blood lead levels are correlated (if at all) with bone lead levels. *Id.* at 214:15-21, 404:12-405:1. Accordingly, studies about blood lead levels lend no support to Dr. Bithoney's opinions.

Second, the studies Dr. Bithoney cites do not address the specific types of injuries that Plaintiffs claim to have sustained. As Michigan law recognizes, toxins frequently cause “different harmful effects at different doses.” *Lowery*, 500 Mich. at 1043-44 (Markman, J., concurring). “As a result, a substance may be harmful at

a certain level of exposure but may not be sufficient to cause a particular adverse health effect.” *Id.* Thus, in order for Dr. Bithoney’s opinions to be relevant to this case, he must identify the level of exposure necessary to cause Plaintiffs’ specific injuries. *Id.*; see *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996) (“[T]here must be evidence from which the factfinder can conclude that the plaintiff was exposed to levels of that agent that are known to cause the kind of harm that plaintiff claims to have suffered.”).

Dr. Bithoney ignores this requirement. Although he cites various studies suggesting an association between low blood lead levels and certain adverse cognitive effects, he does not explain how these studies relate (if at all) to Plaintiffs’ particular cognitive or behavioral conditions. For example, none of these studies looked for an association between lead exposure and [REDACTED] at any level of exposure, much less found an association at blood lead levels below [REDACTED]. When the studies *do* include the specific types of cognitive or behavioral effects at issue here, they frequently fail to find any association at all or conclude that an association exists only at exposure thresholds above [REDACTED]. For example, Dr. Bithoney testified at his deposition that E.S.’s [REDACTED] was attributable to [REDACTED] lead exposure, Dep. 219:3-5, but the only study in Dr. Bithoney’s report that assessed [REDACTED] found that it “was not related to lead exposure.” Ex. 23, Chiodo 365 (“The [REDACTED] was

not related to lead exposure, suggesting that [REDACTED] [REDACTED].”); *see id.* at 368 (failing to find a statistically significant association between lead exposure and IQ at blood lead levels below [REDACTED] [REDACTED]); Ex. 22, Lanphear 526 (failing to find a statistically significant association with performance on visual reasoning tests or working memory tests at blood lead levels below [REDACTED]).

Third, the sources Dr. Bithoney cites do not suggest an association, much less a causal relationship, between any health effects and blood lead levels similar to Plaintiffs’ blood lead levels. As an initial matter, two of the sources cited in Dr. Bithoney’s report—the Chiodo and Lanphear studies—are cross-sectional studies, which are limited in their ability to establish causation. Although cross-sectional studies may suggest that a condition is more prevalent among individuals exposed to a particular substance, it cannot establish a causal relationship because it is impossible to know whether the exposure preceded the disease. Fed. Jud. Ctr., *Reference Manual* 560-61; *see In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1323-24 n.57 (N.D. Fla. 2018) (discussing limited usefulness of cross-sectional studies and noting that “[t]emporal and/or causal relationships between exposure and disease or outcome cannot be established through a cross-sectional study”); *U.S. v. W.R. Grace*, 455 F. Supp. 2d 1181, 1189-90 (D. Mont.

2006) (noting that “cross-sectional studies are the least desirable epidemiological studies when it comes to reaching reliable conclusions about causation”).

Further, neither the Chiodo nor the Lanphear study demonstrate that very low exposure levels, [REDACTED], are capable of causing their injuries. In the Chiodo study, the researchers saw statistically significant associations between exposures above [REDACTED] and a number of neurobehavioral outcomes (*e.g.*, performance IQ, block design, and off-task behaviors), but few such associations when blood lead levels fell below [REDACTED]. Ex. 23, Chiodo 368 (finding a statistically significant relationship with respect to just 3 of 15 outcomes at levels below [REDACTED]). Similarly, in the Lanphear study, the researchers failed to find a statistically significant relationship between exposure and any of the four cognitive measures studied at blood lead levels of [REDACTED] or lower. Ex. 22, Lanphear 528.

Finally, Dr. Bithoney’s claim that the Schwartz study demonstrates that blood lead levels as low as [REDACTED] are capable of causing adverse health effects is wrong. Contrary to Dr. Bithoney’s report, the Schwartz study did not conclude that “[e]ven concentrations down to [REDACTED] were found to have an impact” on cognition. Report (E.S.) 11. Instead, Schwartz reported only that the data showed “*no evidence of a threshold*” down to blood lead concentrations of [REDACTED]. Ex. 20, Schwartz 42

(emphasis added). As discussed above, *see* pp. 43-44, *supra*, the failure to identify a threshold at a certain level is not proof of an effect at that level.

C. Dr. Bithoney Did Not Reliably Exclude Alternative Sources Of Lead

To prove causation under Michigan law, a toxic-tort plaintiff must produce evidence that “excludes other reasonably relevant potential causes of [the] plaintiff’s symptoms.” *Powell-Murphy*, 2020 WL 4722070, at *5 (internal quotation marks omitted). That requires a “differential etiology,” which is sometimes called a “differential diagnosis.” *Pluck*, 640 F.3d at 678. As the Sixth Circuit has repeatedly explained, “[d]ifferential diagnosis is ‘a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.’” *Id.* (quoting *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001)).

An expert who offers an opinion on specific causation in a toxic-tort case must perform a reliable differential etiology. *See Pluck*, 640 F.3d at 680 (affirming exclusion of expert’s testimony with respect to specific causation because the expert “failed to ‘rule out’ alternative causes of [the plaintiff’s illness]” other than the claimed exposure to benzene, “as is required under the differential-diagnosis methodology”); *Nelson*, 243 F.3d at 253 (expert’s opinion that exposure to PCBs caused the plaintiffs’ claimed injuries was unreliable because “there was simply no

basis for [the expert's] assumption that PCBs, and not one of numerous other factors, was the cause of plaintiffs' reported maladies").

A differential etiology requires three steps: The expert must "make an accurate diagnosis of the nature of the disease"; "reliably rule in the possible causes of it"; and "reliably rule out the rejected causes." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010). If the expert does not identify alternative causes of disease and "reliably rule out the rejected causes," then "the court must exclude the ultimate conclusion reached." *Id.*

Dr. Bithoney's reports do not identify any possible alternative causes of Plaintiffs' asserted medical conditions other than lead exposure, much less systematically consider and rule out other possible causes. When Dr. Bithoney was asked at his deposition whether and how he "ruled out" possible alternative causes, he testified that he considered "family history, educational history of the parents, et cetera," Dep. 221:11-19, but did not provide any additional detail. Although family history and parents' education may be part of a reliable differential etiology, they are not sufficient. This is particularly true when, as here, there are a number of possible alternative causes. These alternative causes run the gamut from exposure to various other toxins (*e.g.*, methylmercury, arsenic, solvents, industrial chemicals, phthalates, polyhalogenated organic molecules, and bisphenol A) to a variety of maternal characteristics (*e.g.*, maternal obesity, alcohol consumption, hypertension,

and acetaminophen use). Ex. 9, Weed Report 40. Because nothing in either Dr. Bithoney's reports or his deposition testimony suggests that he employed a "reliable" and "scientific" differential etiology to rule out causes other than lead, *Tamraz*, 620 F.3d at 673-74, his specific causation opinion should be excluded.¹⁰

In addition to failing to consider causes other than lead, Dr. Bithoney's differential etiology fails to consider sources of lead other than Flint's water. *Pluck*, 640 F.3d at 680 (affirming district court's order excluding expert because he failed to rule out other sources of benzene exposure); see *Rutigliano v. Valley Bus. Forms*,

¹⁰ Dr. Bithoney said that he also relied on Dr. Krishnan's opinion that [REDACTED] were "consonant with lead intoxication." Dep. 221:14-19. Plaintiffs have represented to the Court that they are not relying on Dr. Krishnan's opinions to establish causation. See Tr. of Oct. 4, 2020, Hearing 5:20-6:14, *In re Flint Water Litig.*, No. 16-cv-10444 ECF No. 1285, Page ID.38733-38734; see also Ex. 29, Krishnan Dep. 18:2-23 ("Dr. Krishnan is not going to be attempted by us [Plaintiffs] to be qualified as an expert who could talk about why her observations were caused, what caused them.").

Moreover, Dr. Krishnan has no experience or training in the field of etiology (*i.e.*, the science of determining disease causation), see Ex. 12, Krishnan CV, and is not qualified to offer opinions on whether Plaintiffs' claimed injuries may have been caused by lead exposure. See *Tamraz*, 620 F.3d at 671-73 (disqualifying neurologist from testifying about the cause of disease because the doctor had unquestioned expertise in diagnosis but lacked expertise in etiology). Accordingly, Dr. Bithoney cannot bolster his opinions by invoking Dr. Krishnan's views.

In any event, even if Plaintiffs' alleged impairments were consistent with lead exposure, that would not suffice to either "rule in" lead exposure as the cause of those impairments or "rule out" other potential causes. See *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994) (opinion that symptoms were "consistent with" toxic exposure did not demonstrate causation); *Cowan*, 2007 WL 3203249, at *2 ("[T]he fact that Plaintiffs had symptoms consistent with toxic exposure is insufficient to establish the requisite causal connection.").

929 F. Supp. 779, 790-91 (D.N.J. 1996) (excluding expert who failed to analyze the plaintiff's home or other environments to identify other possible sources of formaldehyde exposure). That is particularly critical here, because lead is ubiquitous. As Dr. Bithoney testified, children are exposed to lead from a variety of "fairly typical" sources, including lead paint, lead dust, and lead in soil. Dep. 37:3-9.

Water is just one possible source of lead exposure. Dr. Bithoney acknowledged that lead-contaminated water accounts for just 20% of the lead to which children are exposed. *Id.* at 207:6-208:8. By comparison, soil and dust account for over 50% of the average child's lead exposure. Ex. 8, Finley Report 31 ("Typically, the combination of lead contaminated soil and indoor dust constitute the majority of lead exposure in a child's environment."). Indeed, Congress recently has concluded that even baby food can be a source of lead (as well as other heavy metals that can cause cognitive effects, such as arsenic, cadmium, and mercury). *See* Ex. 16, H. Comm. on Oversight and Reform, Subcomm. on Econ. and Consumer Pol'y, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021).

Beyond asking Plaintiffs' parents whether they had evidence of other sources of exposure, Dr. Bithoney did nothing to assess whether these alternative exposure sources may have been the cause of Plaintiffs' injuries. Dep. 225:12-226:11. Dr.

Bithoney's assertion that he had "no evidence" that Plaintiffs were exposed to lead from alternative sources, *id.* at 226:4-6, does not satisfy his burden, because he did not bother to investigate alternative sources. *See State Farm*, 980 F. Supp. 2d at 1039 (excluding testimony of expert who relied on information provided by party and neither performed additional investigation nor sought to verify the reliability of the information); *Avila v. Willits Env't Remediation Trst.*, 2008 WL 360858, at *10 (N.D. Cal. Feb. 6, 2008) (excluding specific-causation testimony because expert failed to investigate and consider alternative sources of dioxin and "assumed that any dioxin exposure 'must' have come from" the defendant's plant).

Had Dr. Bithoney conducted an investigation into alternative sources of potential lead exposure, he would have found that Plaintiffs were exposed to lead dust in their homes, lead contaminated soil, and in at least two cases, lead paint. Ex. 8, Finley Report 30-64 (analyzing alternative sources of lead in Plaintiffs' homes and estimating their relative contributions to Plaintiffs' blood lead levels). He also should have, but did not, ask Plaintiffs' parents about the brands of baby food that Plaintiffs ate as infants. Dr. Bithoney's failure to identify these sources, much less rule them out as potential causes of Plaintiffs' alleged injuries, renders his opinion unreliable.

Finally, Dr. Bithoney did nothing to exclude the possibility that water consumption *before* the Flint water crisis caused Plaintiffs' alleged injuries. Dr.

Marc Edwards—a professor at Virginia Tech, who was one of the first experts to discover the problems with Flint water, concluded that there was a significant spike in water lead levels in Flint in 2011. *See* Ex. 11, Duquette Report 6-7; Ex. 8, Finley Report 17. Plaintiffs E.S., A.T., and D.W. were all living in Flint at the time. *See* Ex. 6, Pl.’s Fact Sheet (E.S.) 6; Ex. 32, Martin Dep. 11:23-24, 56:19-29; Ex. 33, Teed Dep. 17:23-18:11.¹¹ There is no evidence that any of these three Plaintiffs refrained from consuming unfiltered Flint tap water at that time. Indeed, because no one knew about the 2011 spike at the time, Ex. 8, Finley Report 17, these plaintiffs likely did consume Flint tap water in 2011. Dr. Bithoney thus cannot “rule out” the possibility that these Plaintiffs were injured entirely by exposure to lead in Flint tap water before VNA arrived in Flint.

III. Dr. Bithoney’s Opinions About Plaintiffs’ Potential Future Injuries Are Unreliable

Dr. Bithoney’s opinions on the potential future effects of Plaintiffs’ alleged injuries are also unreliable. As support for his opinion that Plaintiffs will [REDACTED]

[REDACTED]

[REDACTED] Dr. Bithoney relies on research related to the “so-called lag effect” associated with certain types of brain injury. Report (E.S.) 13; Report (A.T.) 12; Report (R.V.) 12; Report (D.W.) 12. However, none of the

¹¹ R.V. was [REDACTED]. *See* Ex. 7, Pl.’s Fact Sheet (R.V.) 6.

research suggests that this lag effect is inevitable, or even expected, whenever there is any form of brain injury. Instead, this effect is part of a “theoretical model” used to describe a phenomenon sometimes seen in certain types of brain injury (*e.g.*, Traumatic Brain Injury, medullablastoma, or cranial radiation treatment). *See* Ex. 26, Maureen Dennis, *et al.*, *Functional Plasticity in Childhood Brain Disorders*, 24 *Neuropsychology Rev.* 389 (2014) at 4-6. Because Dr. Bithoney cites no evidence that the lag effect has been observed in the case of toxic exposures generally, much less exposures to [REDACTED], his opinion that it will occur is unreliable. *Joiner*, 522 U.S. at 146 (“Trained experts commonly extrapolate from existing data. . . . [But] a court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”).

Dr. Bithoney’s opinion that Plaintiffs are at an increased risk of experiencing various physical conditions, [REDACTED], is similarly inadmissible. In offering this opinion, Dr. Bithoney appears to rely on a single “fact sheet” prepared by the NIH for the general public that purports to describe various health effects associated with lead exposure. Report (E.S.) 11 (citing Ex. 19, NIH). With respect to the various physical conditions Dr. Bithoney identifies, the NIH’s fact sheet states that “[b]lood lead levels below [REDACTED] are associated with [REDACTED]” NIH [REDACTED]

2. Notably, the NIH document does not state that such an association exists with respect to childhood exposures, does not say anything about a “higher likelihood” of experiencing these various medical illness in adulthood, does not provide any information on the strength of the association, does not say how far below [REDACTED] such effects are found, and does not even identify the research upon which the statement is based. *Id.*; Ex. 9, Weed Report 71-72. This single fact sheet does not support Dr. Bithoney’s opinion that Plaintiffs—[REDACTED]
[REDACTED]—face an increased risk of experiencing these specific physical conditions.

IV. Dr. Bithoney’s Opinions Do Not Fit Plaintiffs’ Theory Of Liability With Respect To VNA

Finally, Dr. Bithoney’s opinions should be excluded on the ground that they do not fit Plaintiffs’ theory of liability with respect to VNA. For expert testimony to meet the helpfulness requirement of Rule 702, there must be “a ‘fit’ between the testimony and the issue to be resolved by the trial.” *Greenwell v. Boatwright*, 184 F.3d 492, 496 (6th Cir. 1999). As the Sixth Circuit has explained, that requires “a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify.” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592).

Dr. Bithoney’s opinion lacks the necessary fit to Plaintiffs’ theory of liability against VNA. He opines that Plaintiffs’ alleged injuries are attributable to having

ingested Flint water during the water crisis. However, Flint did not engage VNA until February 2015. Thus, in order for Dr. Bithoney's opinions on the cause of Plaintiffs' injuries to "fit" their theory of liability with respect to VNA, his opinions must address whether Plaintiffs' conditions are attributable to their ingestion of lead in Flint tap water *after* February 2015. Dr. Bithoney does not address that at all.

First, Dr. Bithoney's interviews with Plaintiffs' parents do not provide any evidence that Plaintiffs' conditions were caused by water they drank after VNA was engaged. If anything, they establish the opposite. Dr. Bithoney states that each of the Plaintiffs stopped drinking tap water at home altogether or reduced the amount of tap water he or she drank before VNA was engaged. *See* pp. 5-6, *supra* (discussing testimony of Plaintiffs' mothers about when they stopped drinking Flint tap water). Additionally, Plaintiffs' bone lead results, which are the linchpin of Dr. Bithoney's exposure assessments, provide no information about where the lead came from or when. They therefore cannot support an opinion that Plaintiffs were exposed to a harmful amount of lead as a result of consuming Flint water after VNA began its engagement in February 2015. Dr. Bithoney does not identify any other way of attributing Plaintiffs' alleged conditions to tap water they ingested after February 2015, as opposed to tap water they ingested earlier in the water crisis, tap water they ingested before the water crisis (*e.g.*, in 2011), other sources of lead, or other potential causes having nothing to do with lead.

Because Dr. Bithoney does not and cannot opine that Plaintiffs' conditions were caused (in whole or in part) by their consumption of Flint tap water after February 2015, his opinions do not fit Plaintiffs' claims against VNA and would not be helpful to the jury. Accordingly, they should be excluded.

CONCLUSION

The Court should exclude the testimony and reports of Dr. William Bithoney.

Respectfully submitted,

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Dated: May 11, 2021

CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2021, I electronically filed the foregoing document with the Clerk of the Court using the ECF System, which will send notification to the ECF counsel of record.

Respectfully submitted,

/s/ James M. Campbell

Dated: May 11, 2021